

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 20

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JOSEPH P. VACANTI, LINDA G. CIMA
and MICHAEL J. CIMA

Appeal No. 1998-2777
Application 08/477,226¹

HEARD: November 17, 1999

Before STONER, Chief Administrative Patent Judge, FRANKFORT, and BAHR, Administrative Patent Judges.

FRANKFORT, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal from the examiner's refusal to allow claims 1 through 36 as amended subsequent to the final rejection in a paper filed September 3, 1996 (Paper No. 10). Claims 1

¹ Application for patent filed June 7, 1995. According to appellants, this application is a continuation-in-part of Application 08/200,636, filed February 23, 1994, now U.S. Patent No. 5,518,680, granted May 21, 1996, which is a continuation-in-part of Application 08/138,345, filed October 18, 1993, now U.S. Patent No. 5,490,962, granted February 13, 1996.

through 36 are all of the claims pending in the application.

Appellants' invention relates to a method for making devices used for tissue regeneration (claim 1), which method uses computer-aided-design (CAD) in combination with solid free-form fabrication technology to form vascularized polymeric matrix structures which can be implanted and connected to ducts within tissue in a patient, seeded with cells, and allowed to form new tissue that is supplied with adequate blood-borne nutrients via the predesigned vasculature. In addition, appellants' polymeric matrix structures or devices for tissue regeneration may be formed to have therein other predesigned lumens and ducts for exocrine, excretory, and other functions associated with normal tissue *in vivo*. Claim 16 on appeal is directed to a medical device for tissue regeneration formed in accordance with the foregoing method. A copy of independent claims 1 and 16 can be found in the Appendix to appellants' brief.

The prior art references relied upon by the examiner in rejecting the appealed claims are:

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| Klebe | 5,108,926 | Apr. 28, 1992 |
| Cima et al. (Cima '380) | 5,387,380 | Feb. 7, 1995 |

Claims 1 through 36 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which appellants

Appeal No. 1998-2777
Application 08/477,226

regard as their invention.

Appeal No. 1998-2777
Application 08/477,226

Claims 1 through 3, 8 through 10, 12 through 18, 23 through 25, 27 through 29 and 32 through 36 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Klebe.

Claims 4 through 7, 11, 19 through 22 and 26 stand rejected under 35 U.S.C. § 103 as being unpatentable over Klebe in view of Cima '380.

Claims 30 and 31 stand rejected under 35 U.S.C. § 103 as being unpatentable over Klebe.

Rather than attempt to reiterate the examiner's full commentary with regard to the above-noted rejections and the conflicting viewpoints advanced by the examiner and appellants regarding the rejections, we make reference to the examiner's answer (Paper No. 16, mailed June 20, 1997) for the reasoning in support of the rejections, and to appellants' brief (Paper No. 15, filed March 31, 1997) for the arguments thereagainst.

OPINION

In reaching our decision in this appeal, we have given careful consideration to appellants' specification and claims, to the applied prior art references, and to the respective positions

articulated by appellants and the examiner. As a consequence of our review, we have made the determinations which follow.

Looking first at the examiner's rejection of claims 1 through 36 under 35 U.S.C. § 112, second paragraph, we note that we see nothing indefinite about appellants' use of the language "seeding with cells" as set forth in independent claims 1 and 16 on appeal. The examiner's statement (answer, pages 3-4) that the recitations of claims 1 and 16 are "indefinite in that it is unclear whether or not 'seeding with cells' should be set-off" is not otherwise explained by the examiner and is simply not understood. Exactly what action the examiner seeks on appellants' part is not clear and exactly what the examiner means by "set-off" is likewise unclear. As for the examiner's concern that the scope of claim 1 on appeal is not commensurate with the preamble of claim 1, we understand from appellants' disclosure as a whole that a "device" formed in accordance with the method set forth in claim 1 comprises a matrix structure like that defined in the body of claim 1. Thus, we are of the opinion that one of ordinary skill in the art would readily recognize that the device set forth in the preamble of claim 1 is comprised of the matrix as defined in the body of the claim, and that the method of claim 1 on appeal thus defines appellants' invention with a reasonable degree of precision and particularity adequate to satisfy the requirements of 35 U.S.C. § 112, second paragraph.

With regard to the examiner's comments directed at dependent claims 2 and 3 on appeal (answer, page 4), we perceive that each of these claims sets forth the step of "forming interconnected lumens within the matrix," which lumens are specifically adapted for or capable of being connected to specifically recited vessels or ducts within tissue of a patient, i.e., blood vessels (claim 2), or a duct selected from the group consisting of "lymph ducts, exocrine function ducts, excretory ducts, and ducts for neural ingrowth" (claim 3). These limitations in claims 2 and 3 clearly provide a further limitation on the method of claim 1 in that the interconnected lumens recited in clause (b) of claim 1 must be formed in such a manner, size, etc., as to have the capability of being connected to a blood vessel (claim 2) or one of the ducts set forth in claim 3 on appeal.

Since we have found that appellants' claims on appeal are reasonably definite, it follows that the examiner's rejection of claims 1 through 36 under 35 U.S.C. § 112, second paragraph, will not be sustained.

Regarding the examiner's rejection of claims 1 through 3, 8 through 10, 12 through 18, 23 through 25, 27 through 29 and 32 through 36 under 35 U.S.C. § 102(b) as being anticipated by Klebe, we share appellants' view that Klebe fails to teach, disclose or suggest a device for tissue regeneration, or method of making such a device, wherein the device is comprised of a matrix of successive layers of

a biocompatible material laid down using solid free-form fabrication techniques, and wherein said matrix includes “interconnected lumens within the matrix having openings for connection to ducts within tissue in a patient,” as required in each of appellants’ independent claims on appeal. The examiner’s position (answer, pages 11-12) is that because Klebe mentions a three-dimensional tissue structure of cells which have been precisely positioned and arranged with accuracy in a matrix, such a tissue structure or matrix “would inherently include interconnected pores and lumens throughout.” We find no basis in Klebe to reach such a conclusion and the examiner has pointed to none.

In our opinion, the examiner’s position is totally without support in the applied reference and is entirely based on speculation and conjecture. In this regard, we note that it is well settled that inherency may not be established by probabilities or possibilities, but must instead be “the natural result flowing from the operation as taught.” See In re Oelrich, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981). In the present case, neither the Klebe patent nor the examiner provides an adequate factual basis to establish that the natural result flowing from following the teachings of that patent would be a device or matrix structure like that claimed by appellants, wherein interconnected lumens within the matrix are present and capable of being connected to ducts within tissue in a patient, such as blood vessels, lymph ducts, exocrine function ducts, excretory ducts, etc.

While there may certainly be pores or lumens formed in the three-dimensional tissue structure of Klebe, there is no basis to conclude that the tissue structure or matrix in Klebe would necessarily include “interconnected lumens” having openings for connection to ducts within tissue in a patient. Accordingly, since all the limitations of appellants’ claims 1 through 3, 8 through 10, 12 through 18, 23 through 25, 27 through 29 and 32 through 36 are not found in Klebe, either expressly or under principles of inherency, it follows that the examiner's rejection of those claims under 35 U.S.C. § 102(b) relying on Klebe will not be sustained.

As a result of our treatment of independent claim 16 above, it follows that the examiner's rejection of dependent claims 30 and 31 under 35 U.S.C. § 103 based on Klebe alone will likewise not be sustained.

As a further commentary, with regard to the examiner’s rejection of claims 4 through 7, 11, 19 through 22 and 26 under 35 U.S.C. § 103 as being unpatentable over Klebe in view of Cima ‘380, we note that we share appellants’ view (brief, pages 13-15) that it would not have been obvious to one of ordinary skill in the art, based on the teachings of Klebe and Cima ‘380, to merely employ the three-dimensional printing techniques described in Cima ‘380 in the construction of a three-dimensional tissue structure like that disclosed in Klebe. Contrary to the examiner’s determination (answer, page 7), we

find nothing in Cima '380 which "teaches three-dimensional printing techniques for the formation of three-dimensional tissue structures" (emphasis added) as the examiner seems to believe is present in Cima '380 at column 2, line 65 -column 3, line 20. There is absolutely no mention in the portion of Cima '380 relied upon by the examiner of "three-dimensional tissue structures," instead the reference specifically mentions "molds for metal casting," "pre-forms for metal matrix composites" and that the techniques therein may be used to form plastic components or parts for various purposes. Thus, the examiner's rejection of claims 4 through 7, 11, 19 through 22 and 26 under 35 U.S.C. § 103 as being unpatentable over Klebe in view of Cima '380 will also not be sustained.

In view of the foregoing, the examiner's decision rejecting claims 1 through 3, 8 through 10, 12 through 18, 23 through 25, 27 through 29 and 32 through 36 under 35 U.S.C. § 102(b) and claims 4 through 7, 11, 19 through 22, 26, 30 and 31 of the present application under 35 U.S.C.

Appeal No. 1998-2777
Application 08/477,226

§ 103 is reversed. In addition, the examiner's decision rejecting claims 1 through 36 under 35 U.S.C. § 112, second paragraph, is also reversed.

REVERSED

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| BRUCE H. STONER, JR. |) | |
| Chief Administrative Patent Judge |) | |
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| |) | BOARD OF PATENT |
| CHARLES E. FRANKFORT |) | APPEALS |
| Administrative Patent Judge |) | AND |
| |) | INTERFERENCES |
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Appeal No. 1998-2777
Application 08/477,226

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